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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,829

03/23/2005

Andrew Lennard Lewis

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,829	<b>Applicant(s)</b> LEWIS ET AL.	
	<b>Examiner</b> PAUL DICKINSON	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51, 53, 71, 75 and 77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51, 53, 71, 75, and 77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 3/20/2009 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51, 53, 71, 75 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0023054 (WO '054) in view of US 6150432 ('432). '452 discloses a method of treatment of an animal, comprising administering a therapeutic or diagnostic composition comprising particles comprising a core which is polyvinyl alcohol (a water-insoluble water-absorbing non-biodegradable polymer) matrix into which is absorbed aqueous liquid, the particles having diameters in the range of 10 to 2000 microns, to form an embolus for therapy or diagnosis (see abstract; page 4, line 2 to page 6, line 18). The particles are sterile (see page 13, lines 23-27). The particles may be substantially spherical (see page 6, lines 26-29; page 10, line 29 to page 11, line 3). Conditions and diseases that can be treated with the method include embolization of vessels around tumours or tumour-excision sites (see page 14, line 29 to page 15, line 20).

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The surfaces of the microparticles of WO '054 do not express zwitterionic groups.

'432 discloses the blending of two polymers, polymer (A) and polymer (B), polymer (A) being a polymer bearing zwitterionic pendant groups, and polymer (B) being a polymer already known for a particular application (see abstract). The addition of polymer (A) to polymer (B) increases the biocompatibility of polymer (B), and provides decreased fibrinogen absorption and/or platelet activation (see abstract). The blend has application in vascular implants (see Table 1). Polymer (A) may be YBX as defined in instant claim 51 (see col 3, lines 24-62; col 5, lines 23-35). Y may specifically be  $H_2C=CR-CO-A$  where R is hydrogen or  $C_{1-4}$  alkyl and A is  $-O-$  or  $-NR^1-$  where  $R^1$  is  $C_{1-4}$  alkyl or BX, which satisfies instant claim 75. Polymer (B) may be polyvinyl alcohol (see Table 1). In these blends, the zwitterionic group is bound at the surface (see col 25, lines 9-19).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the teachings of WO '054 and '432, to provide an improved embolization material. Specifically, it would have been obvious to prepare embolization microspheres from a blend of the polyvinyl alcohol polymer of WO '054 and the YBX polymer of '432. In this way, the embolization microspheres will have decreased fibrinogen absorption and/or platelet activation, which are desirable traits of embolization materials. The expectation of success is high, as WO '432 already demonstrates the ability of polyvinyl alcohol alone to serve as an embolization material, and '432 teaches

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that blending YBX with polyvinyl alcohol increases the biocompatibility of the polymer, while decreasing potential fibrinogen absorption and/or platelet activation. Regarding the microparticle diameter range, it would have been obvious to optimize this parameter, through routine experimentation, to improve the efficacy of the formulation. In this way, one would find Applicant's claimed range of 40 to 4000 microns, as this overlaps with the range taught by WO '054 of 10 to 2000 microns. See MPEP § 2144.05, II. Regarding the diameter of the particles when fully imbued with water, the references fail to disclose this property. However, as a composition cannot be separated from its properties, it is the position of the Examiner that the particle formulation rendered obvious by WO '054 in view of '432 would inherently have this property. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number

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is (571)270-3499. The examiner can normally be reached on Mon-Thurs  
9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the  
examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616.  
The fax phone number for the organization where this application or proceeding  
is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from  
the Patent Application Information Retrieval (PAIR) system. Status information  
for published applications may be obtained from either Private PAIR or Public  
PAIR. Status information for unpublished applications is available through  
Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR  
system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-  
free). If you would like assistance from a USPTO Customer Service  
Representative or access to the automated information system, call 800-786-  
9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

June 12, 2009